REMARKS

Claims 1-6 and 8-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Silverman *et al.* (U.S. Patent No. 6,248,058). Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Silverman *et al.* (U.S. Patent No. 6,248,058). Reconsideration and allowance of all claims is respectfully requested.

Silverman et al. disclose a method for treating a tracheo-esophageal fistula. Specifically, apparatus or medical device 21 shown therein includes a needle assembly 26 slidably carried by probe 22. See Column 2, lines 41-44. Probe 22 includes a flexible elongate tubular member or insertion tube 31. See Column 2, lines 50-53. A working passageway or channel 51 is further provided in insertion tube 31 and extends to a side port 52 formed in handle 33. FIG. 1; Column 3, lines 9-11. Sleeve 62 has a lumen extending longitudinally therethrough for receiving the needle 61. Sleeve 62 and the needle 61 are slidable relative to each other in a longitudinal direction. Referring to FIG. 1, a screw 179 extends between arms 176 for locking the arms to grip 82 and thus longitudinally locking sleeve 62 relative to needle 61. Column 6, lines 39-41. The physician causes sharpened end 67 of needle 61 to penetrate wall 188 by moving the needle 61 and sleeve 62 closer to side port 52. Column 12, lines 49-51.

Claim 1 is patentable by calling for an injection device for use with a probe of the type set forth therein including, among other features, a needle assembly slidably disposed in the tubular member, the needle assembly having a column strength when locked within the tubular member so as not to buckle during puncture of the tissue by the needle and thus limit retraction of the needle assembly relative to the tubular member during puncture of the tissue and provide substantially one-to-one movement between the proximal and distal extremities of the needle assembly.

Silverman et al., while disclosing a screw 179 that longitudinally locks sleeve 62 relative to needle 61, is silent with respect to a needle assembly having a column strength when locked within a tubular member so not to buckle during puncture of the tissue by the needle and thus limit retraction of the needle assembly relative to the tubular member during puncture of the tissue and provide substantially one-to-one movement between the proximal and distal extremities of the needle assembly.

In fact, the issues raised by the Examiner in the present Office Action have been previously addressed by Applicant in response to earlier Office Actions. In particular, the Examiner cites Silverman et al., U.S. Patent No. 6,248,058 (the "Silverman '058 patent") in support of the present 35 U.S.C. 102(b) rejection. However, the Examiner relies on disclosure within the Silverman '058 patent which was also present in Silverman et al., U.S. Patent No. 6,251,063 (the "Silverman '063 patent") to support the rejection. *Compare Column 4, lines 32-35; Column 4, line 66 – Column 5, line 2; Column 5, lines 18-21; Column 8, lines 18-20; Column 9, lines 35-41 of the Silverman '063 Patent with the cited language of the Silverman '058 patent in the present Office Action.*

As the Examiner has already stated, Silverman et al. do not disclose a "second tubular member to have sufficient column strength to prevent buckling and provide substantially one-to-one movement between the proximal and distal extremities of the second tubular member." See Office Action dated September 7, 2007, pg. 3, referring to the Silverman '063 patent. The Examiner has not set forth any disclosure in the Silverman '058 patent contrary to this statement, nor could such disclosure be found therein.

Instead, the Examiner argues in the present Office Action that "the needle member must have sufficient column strength to prevent buckling as it is inserted into the tissue or else it would be impossible to puncture the tissue and the device would be useless." Office Action, Pg. 2. As Applicant previously explained in its response to the Office Action of January 29, 2007 (which the Examiner found to be persuasive at Pg. 5 of the Office Action dated September 7, 2007), the device disclosed in Silverman et al. would not be "useless" as suggested by the Examiner. As indicated above, Silverman et al. discloses needle 61 may penetrate wall 188 by a physician moving the needle 61 and sleeve 62 closer to side port 52. See the Silverman '058 patent, Column 12, lines 49-51. Due to the general physical composition and nature of a needle, it is likely that such a needle as disclosed in Silverman '058 can be inserted into tissue by the application of force. However, the accuracy of placement of the needle is hindered to the extent buckling is not restricted. In this regard, it is stated in the "Background" portion of the present application at Page 1, lines 14-17:

> Medical devices have been provided for the delivery of an implant-forming material to various portions of the wall forming a vessel such as the gastrointestinal tract of a mammalian body. See, for

example, U.S. Patent No. 6,251,063 [the Silverman '063 patent]. There remains, however, a need for increased accuracy in the placement of such material and the implants formed thereby.

As Applicant has previously discussed, increasing the accuracy in placing implants by use of a needle is an important feature of the invention. Enhancing the placement accuracy of the needle serves to inhibit damage to the mucosal layer and other adjacent muscle layers from improperly placed material. See Detailed Description, Page 17, lines 13-15. Specifically, the limiting of the longitudinal travel or retraction of needle, which is carried by the needle assembly, relative to tubular member permits greater accuracy in the placement depth of the needle in the targeted tissue, thus facilitating relatively consistent puncture depths between injection sites. See Page 20, lines 24-26. Since contraction has been limited, as claimed, by the increased column strength of the needle assembly when locked within the tubular member, the amount of advancement of needle into the probe translates essentially one-to-one with the amount that needle is advanced into the tissue. See Page 20, lines 29-33. Silverman et al. is silent with respect to such an improvement.

Claims 2-11 depend from Claim 1 and are patentable for the same reasons as Claim 1 and by reason of the additional features set forth respectively therein.

Claim 12 is patentable by calling for an injection device of the type set forth therein including, among other features, a first tubular member having a proximal extremity with a proximal opening and a distal extremity, the proximal extremity of the first tubular member having a port distal of the proximal opening, a reservoir of the biocompatible solvent coupled to the port for clearing any of the biocompatible composition that clogs the first tubular member distal of the port. Similar to that previously discussed by Applicant in a prior response to Office Action, insertion tube 31 of Silverman et al. does not also have a port distal of proximal opening 52 or such port coupled to a reservoir of biocompatible solvent for clearing any of the biocompatible composition that clogs the first tubular member distal of the port. See FIG. 1 of Silverman et al. Accordingly, Silverman et al. does not disclose Applicant's claimed invention, as set forth in Claim 12.

Claims 13-15 depend from Claim 12 and are patentable for the same reasons claim 12 and by reason of the additional features called for respectively therein.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

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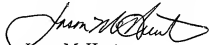

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